**MQSA Requirements for the Mammography Equipment Evaluations (MEE)**

When a mammography facility installs new radiographic equipment (x-ray units or processors), the new equipment must be evaluated by a qualified medical physicist **and the accreditation requirements of the facility's accreditation body must be met before the unit is placed into service** (21 CFR 900.12(e)(10)). In this context, "new" means "new to the facility" and, therefore, includes used equipment. Mammography equipment evaluations must also be performed whenever equipment is disassembled and then reassembled at the same or a new location or whenever a major component is changed or repaired. The MEE is required even if a full survey has recently been completed to verify that all functions, which may have been affected by the change or repair, have been successfully restored.

**Scope of the MEE**

With respect to testing of the equipment, the MEE is more extensive than the survey. It may be regarded as an "acceptance" test for the equipment and an annual survey alone is not sufficient to meet this requirement. The MEE must address all applicable requirements under the equipment section of the regulations (21 CFR 900.12(b)) as well as all applicable QC requirements and testing under 21 CFR 900.12(e), including applicable daily, weekly, quarterly, semiannual, and annual QC tests. Such testing is only applicable to the specific equipment that is repaired, replaced, re-assembled, or added and it is not applicable to other equipment in the facility that has not been affected.

A. For a **newly installed or re-assembled x-ray unit**, the medical physicist must:
    1. Perform all the annual tests listed in section (e)(5) [except (e)(5)(viii), which need not be included if the new unit is not the first one to be accredited in the facility unless new cassettes are being added], the "other modality" tests listed in section (e)(6) (if applicable), the phantom image test listed in section (e)(2), the compression force test listed in section (e)(4)(iii); and
    2. Verify that the new x-ray unit meets the equipment standards listed in sections (b)(1-10). Furthermore, if the new unit is the first and/or the only one at the facility, then Sections (b)(11), (b)(12), (b)(14), and (b)(15), which relate to the screen-film combination and the lighting and viewing conditions used at the facility, respectively, must also be verified.
B. For a **newly installed or reassembled processor**, the medical physicist must perform the following tests/tasks:
    1. Sensitometric strip as described in 21 CFR 900.12(e)(1)
    2. Phantom image quality as described in 21 CFR 900.12(e)(2)
    3. System artifact evaluation as described in 21 CFR 900.12(e)(5)(ix)
    4. Dose determination as described in 21 CFR 900.12(e)(5)(vi) – if clinical techniques increase significantly
    5. Verification of the appropriate processing solutions as described in 21 CFR 900.12(b)(13).

We also recommend that the medical physicist conduct the "Darkroom Fog" test if the integrity of the darkroom is compromised, and to conduct the fixer retention analysis test, if deemed necessary.

Each processor used clinically must have an MEE, even those at remote sites (if any).

C. For a **newly installed or reassembled laser printer**, the medical physicist needs to follow the applicable FFDM QC manual.

Examples of major changes or repairs that would call for an MEE include, but are not limited to:

- Replacement of an x-ray tube, collimator, filter, AEC, or AEC sensor.
- A total overhaul of the processor.

Routine processor preventive maintenance, pump replacement, replacement of the developer or fixer racks, replacement of the control board or changes in chemistry brand are not considered to be major changes or repairs and, consequently, would not require evaluation by a medical physicist.

These evaluations are used by the facility, its accreditation body, and the MQSA inspector to determine whether the new or changed equipment meet the requirements of applicable standards in 21 CFR 900.12(b) and (e). Consequently, the physicist should provide the facility with sufficient documentation that clarifies both the testing performed and the test results. The medical physicist (after consultation with the FDA, if necessary) should decide which tests need to be performed following a particular repair, and should be prepared to explain the rationale behind his or her decision. Before the new or changed equipment is put into service for patient examinations or processing mammograms, the facility must correct all problems relating to the regulations (21 CFR 900.12(e)(10)). There is no provision for a 30-day correction period such as with some QC and physics survey test results.

To get a more detailed list of items/tests that are defined as major repairs and or other tests that require the physicist to conduct in person, consult the PGHS (insert the link), which also provides guidance on many related topics.